



OXFORD VACCINE CENTRE

Oxford Vaccine Centre Biobank

Information Booklet

We would like to thank you for your interest/involvement in an Oxford Vaccine Centre (OVC) research study. We are writing now to see if you would be willing for a small amount of the samples taken in this study to be stored in the Oxford Vaccine Centre Biobank.

This is completely voluntary. Before you make your decision, it is important for you to understand what participation would involve. Please take some time to read the information in this booklet carefully and discuss with others if you wish.

If anything is unclear or you would like further information please feel free to contact a member of the Oxford Vaccine Centre team:

Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital, Oxford, OX3 7LE

Tel: 01865 611400

Email: info@ovg.ox.ac.uk

Thank you for taking the time to consider contributing to the
Oxford Vaccine Centre Biobank.

Oxford Vaccine Centre Biobank. Adult Information Booklet and Consent
Version 7.1 dated 17/08/2018 REC 16/SC/0141

Page 1 of 7

What is Oxford Vaccine Centre Biobank?

You are receiving this information booklet as you are currently taking part in an Oxford Vaccine Centre research study, or are considering doing so. In this study samples of blood or other biological materials are being taken, and with your permission, we would like to:

- Obtain a sample of your genetic material for storage in the Oxford Vaccine Centre Biobank,

and/or

- Store any biological samples such as whole blood (with all the blood cells still present), throat or nose swabs, stool samples or biopsy samples,

and/or

- Store serum in the Oxford Vaccine Centre Biobank after the study you are in has ended (serum is the liquid that remains after all blood cells have been removed from blood).

These samples would be stored in the Oxford Vaccine Centre Biobank.

By collecting genetic samples from thousands of participants across different studies, we hope to understand how genes influence the immune response to immunisation and infectious diseases. Storing biological samples or serum would help us with future research into infection and immunity, for example by helping us assess the level of immunity against an infectious disease within the wider population. This information may in turn help in the understanding of diseases and the development of newer, better vaccines. The samples in the OVC Biobank will also provide an invaluable resource for research into other human diseases.

A researcher can request to use samples from the OVC Biobank, but each request will be reviewed and approved by the OVC Biobank committee, who will ensure that research projects are both ethical and scientifically valid.

Why am I being invited to contribute to the Oxford Vaccine Centre Biobank?

You are being invited to contribute to the Biobank as you are currently taking part in another study being conducted by the Oxford Vaccine Centre, or are considering doing so. Contributing to the Biobank is entirely voluntary, and your decision about whether or not you wanted to do this would not affect your involvement in your study.

What would this involve?

If you agreed to contribute samples to the Oxford Vaccine Centre Biobank it would NOT involve any extra procedures. Instead, these would be obtained from the remainder of the samples obtained during your study. With your permission we may also contact your GP or check NHS immunisation databases to check which vaccines you had previously received. All individuals participating in your study conducted at the Oxford Vaccine Centre are being invited to participate in this additional research.

What are the benefits and risks of taking part in the Biobank?

Taking part in the Biobank would not have any direct benefit to you. The genetic testing would look for naturally occurring variation in the genetic code. You would not be informed of the results of analyses conducted on your samples in the Biobank. Although we may be obtaining details of vaccines you have received, we would not be taking on the responsibility for making sure your immunisations are 'up to date'. As there are no procedures beyond those required for your study, there is no additional risk in participating in the Biobank.

Who will have access to the information obtained in the Biobank?

Any records with your information would be held by the Oxford Vaccine Centre or designated archiving facilities. Your participation in the Biobank would remain confidential; however we may need to inform your GP about your involvement in the Biobank if we need to obtain information about vaccines you have previously received. In order to ensure that the Biobank was being managed correctly, for monitoring and audit purposes your records may be read (but not kept) by staff of the Clinical Trials and Research Governance Office, University of Oxford. Other relevant regulatory bodies would also have access to such records (such as the ethics committee and human tissue authority).

What would happen to the samples stored in the Biobank?

Any samples stored in the Biobank would be labeled with a Biobank number, but not your name. Those testing the samples would therefore not know the name or other personal details of the people providing the samples. Following testing, your samples would continue to be stored in the Oxford Vaccine Centre Biobank for future research.

The researchers in the laboratories testing and analysing your samples will not be able to identify which individual a sample had come from. Should it be necessary to identify your samples at any point (e.g. if you changed your mind and want your samples removed from the Biobank), a request will be made to the OVC Biobank Quality Assurance manager (who is independent of the research teams and will hold the linking information) so that your samples can be removed. This will only be permitted following approval from the OVC Biobank Chief Investigator. This information will be retained for a minimum of five years after the last sample has been either used or disposed of in order to meet regulatory requirements. Also, if you informed us that you had previously had samples taken in another OVC study, with your permission we would temporarily re-establish the connection between stored Biobank samples and your name to allow us to 'link-up' all samples provided by you in different studies.

Testing on the samples stored in the Biobank would be performed either in Oxford or at other laboratories with specific expertise; these laboratories may be located in the United Kingdom, the European Union or elsewhere in the world. Research may be performed in collaboration with external research groups, including pharmaceutical companies. Samples will only be shared where appropriate ethical permission has been given and conditions are in place to ensure the samples are handled correctly.

What else do I need to know?

Consent for having your samples stored in the Biobank is voluntary, and if you do not agree this would not affect your participation in the study in which the samples were obtained, nor your routine care. If you chose to withdraw your samples from the Oxford Vaccine Centre Biobank, we would destroy any unused samples and data so that they cannot be used in future research. Data and samples that have already been used cannot be taken out of that research. The Oxford Vaccine Centre Biobank has the approval of the HRA South Central - Hampshire B Research Ethics Committee. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, we suggest that you contact us, or alternatively the University of Oxford Clinical Trials and Research Governance office on 01865 616480.

What do I do now?

Thank you for considering taking part in the Oxford Vaccine Centre Biobank. If you wish to discuss the Biobank in more detail, please contact us by telephone (01865 611400) or e-mail (info@ovg.ox.ac.uk). Otherwise we will ask whether you wish to contribute to the Oxford Vaccine Centre Biobank at a study visit.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Andrew Pollard', with a large, sweeping flourish underneath.

Prof. Andrew Pollard
Study Chief Investigator
Professor of paediatric Infection and Immunity
Honorary Consultant Paediatrician



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Oxford Vaccine Centre Biobank

Informed Consent Form

Name of Participant: _____ Participant Initials: |__| |__|

Please initial each section if you agree with the statement

I have read the Oxford Vaccine Centre Biobank Adult Information Booklet and Consent (Version 7.1, dated 17/08/2018).	__
I have had the opportunity to ask questions about the Biobank and had them answered.	__
I understand that I am free to refuse participation in the Biobank without affecting my medical care.	__
I understand that my linked data will be retained for a minimum of five years after the last of my samples has been used or disposed of.	__
I am aware that the samples provided and anonymised data may be shared with institutions within the United Kingdom, European Union or the rest of the world.	__
I consider these samples a gift to the University of Oxford and I understand I will not gain any direct personal benefit from this.	__
I agree to take part in this research study.	__

If all above are initialled, meaning “yes”, then please place your initials in the appropriate boxes below:

I agree to you contacting my GP or NHS immunisation databases to find out which vaccines I have previously received.	YES	NO	
I agree that genetic material from my study samples may be stored and used in future vaccine related research. <i>(Please initial 'N/A' if the study team member indicates no genes will be stored)</i>	YES	NO	N/A
I agree that biological samples from my study samples may be stored and used in future vaccine related research. <i>(Please initial 'N/A' if the study team member indicates no biological samples will be stored)</i>	YES	NO	N/A
I agree that my blood serum may be stored and used in future research. <i>(Please initial 'N/A' if the study team member indicates no serum will be stored)</i>	YES	NO	N/A
I have previously provided samples in an Oxford Vaccine Centre study and I agree to staff temporarily re-establishing the connection between stored samples and my name so that samples can be linked. <i>(Please initial 'N/A' if you have not previously provided samples in an Oxford Vaccine Centre study or if you do not know whether this is the case)</i>	YES	NO	N/A
<p>Name:</p> <p>Signature: Date: __ __ __ __ __ __ </p>			
<p>Study Staff Name:</p> <p>Signature: Date: __ __ __ __ __ __ </p>			